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Public Health Service  
Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

CERTIFIED MAIL  
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**WARNING LETTER****FLA-06-08**

December 2, 2005

Craig H. Turtzo, President  
Restorative Products, Inc.  
13560 Wright Circle  
Tampa, Florida 33626

Dear Mr. Turtzo:

During an inspection of your establishment located in Tampa, Florida on June 28 - July 1, 2005, an FDA Investigator determined that your establishment is a manufacturer and distributor of an infrared lamp device (Class 11). These products are devices, as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(h)]. The devices emit energy in the infrared spectrum to provide topical heating for the treatment of minor muscle and joint pain.

The investigator documented violations of the Act causing the devices to be adulterated within the meaning of sections 501(f)(1)(B) [21 USC 351(f)(1)(B)] and 501(h) [21 USC 351(h)] and misbranded within the meaning of section 502(o) [21 USC 352(o)] and 502(t)(2) [21 USC 352(t)(2)] of the Act.

Your device received clearance as an electric heating pad on March 30, 1994 (K931261). On October 19, 2001, FDA corrected this clearance and stated that the device "should have been classified as an infrared lamp rather than an electric heating pad." The clearance letter stated that you could "continue marketing your device as described in your Section 510(k) premarket notification." This 510(k) submission described the device as intended for relief of minor muscle and joint pain and improvement of superficial circulation.

Our inspection determined that your product labeling and internet website promote the Anodyne Therapy System for use in the treatment of wounds and ulcers, loss of protective sensation, gait and balance impairment, and other Diabetic Peripheral Neuropathy conditions, as well as conditions associated with Non-diabetic Neuropathies. Your company is also promoting the Anodyne Therapy System for the treatment of conditions including, but not limited to, soft tissue injuries, Carpal Tunnel Syndrome (CTS), and lymphedema. According to our records, however, you do not have marketing clearance from FDA to distribute into interstate commerce the Anodyne Therapy System for these uses.

The promotion of the Anodyne Therapy System for these uses indicates a major modification in the intended use of the device and requires a new premarket submission. 21 CFR 807.81(a)(3)(ii). Because you do not have marketing clearance from the FDA for these new intended uses, marketing

the Anodyne Therapy System with these claims is a violation of the law. Your promotion and introduction into interstate commerce of this device for uncleared indications renders it adulterated under section 501(f)(1)(B) of the Act, for failure to obtain FDA premarket approval, and misbranded under section 502(o) of the Act, for failure to notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. 21 CFR 807.81(b).

#### *Quality System Regulation*

The above-stated inspection revealed that these devices are adulterated under section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, *Code of Federal Regulations* (CFR), Part 820. Significant deviations observed include, but are not limited to, the following:

1. Your firm failed to establish and maintain procedures for implementing corrective and preventive action. In particular, you do not have a procedure to identify the action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems as required by 21 CFR 820.100(a)(3). Your firm has received 29 reports of burns (thermals) from users of the Anodyne Therapy System from August 2004 to April 2005 and failed to adequately investigate all of the reports and to take effective preventive action (FDA 483, Item #1).
2. Your firm failed to analyze processes, quality records, service records, and other sources of quality data to identify existing and potential causes of non-conforming product, or other quality problems as required by 21 CFR 820.100(a)(1). In particular, your firm failed to analyze in-process rejects and to analyze burn report trends. Your firm only analyzes complaints when the actual device is returned to your facility (FDA 483, Item #10).
3. Your firm's corrective and preventive action (CAPA) procedure does not include a requirement that each CAPA be verified or validated to ensure that such action is effective and does not adversely affect the finished device (FDA 483, Item #9). 21 CFR 820.100(a)(4).
4. Where the results of a process cannot be fully verified by subsequent inspection and test, the process must be validated with a high degree of assurance and approved according to established procedures as required by 21 CFR 820.75(a). Your firm failed to document the validation study of (1) the new Pick & Place and Wave Soldering Equipment which are used to produce printed circuit boards for the Anodyne Therapy device, and (2) to complete adequate validation of the new Inserter device used to produce Array boards as follows:
  - a) Lacks documentation of installation and operation qualification of equipment,
  - b) Fails to establish a high degree of assurance that the device meets specifications and can be manufactured consistently in that only 4 Array boards were included in Performance Qualification; and
  - c) Failed to document settings used for the Performance Qualification (FDA 483, Item #2). 21 CFR 820.75(b)(2).
5. Your firm failed to review, evaluate, and investigate complaints involving the possible failure of a device to meet any of its specifications as required by 21 CFR 820.198(c). Your firm failed to obtain adequate information during the investigation of 7 reports related to patients receiving burns as a result of using the Anodyne Therapy device. During investigation of six reports, your firm failed to determine if the user who sustained the injury received medical treatment, the severity of the burns received, and whether the patient was diabetic. This is a repeat of an observation made during the previous inspection dated July 8, 2003. During the investigation of Complaint #1457

dated 10/29/2004, your firm documented that arrays were repaired, but not what was needed to repair the arrays. During investigation of Complaints #1814 and #1952 dated 1/27/2005, your firm documented that defect(s) were found but there is no documentation of the exact nature of the defect(s) (FDA 483, Item #6).

6. Your firm failed to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained as required by 21 CFR 820.72 (a). In particular, your firm did not establish and maintain procedures for calibrating temperature and speed controls on wave soldering equipment and an oven. (FDA 483, Item #7).

7. Your firm failed to establish and maintain procedures to control environmental conditions that could reasonably be expected to have an adverse effect on product quality as required by 21 CFR 820.70(c). Your firm's soldering work instructions require that sensitive components and circuit boards, when not being worked on, must be enclosed in shielding bags or boxes. The investigator observed a minimum of 10 antistatic bags containing sensitive components and p.c. boards in open bags in the storage area (FDA 483, Item #8).

8. Your firm failed to maintain complete design history records (DHRs) as required by 21 CFR 820.184(d). Your DHR fails to include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record (DMR). Your firm fails to document the visual inspection by magnification of p.c. boards after wave soldering (FDA 483, Item #3).

9. A design history file (DHF) must contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan as required by 21 CFR 820.30(j). Your firm's DHF fails to demonstrate that the design was developed following the approved design plan and the design control requirements, e.g., (a) your firm lacks documentation of design verification, design review, design validation, risk analysis, approval by a designated official, and the effective date of a design change made to wiring of arrays for the Anodyne Therapy device which was first released on 5/26/2005 (FDA 483, Item #4).

10. Your firm failed to designate a responsible individual(s) to review for adequacy and approve prior to issuance all documents established to meet the QSR requirements. The approval, including the date and signature of the individual(s) approving the document, shall be documented as required by 21 CFR 820.40(a). Approval of your firm's procedure for testing the temperature of arrays did not have a signature and an effective date (FDA 483, Item #11).

#### *Medical Device Reporting (MDR)*

The above stated inspection also revealed that these devices are misbranded under section 502(t)(2) of the Act (21 U.S.C. 352(t)(2)), in that your firm failed to furnish material or information as required under section 519 of the Act and regulations implementing that section at Title 21 Code of Federal Regulations (21 CFR), Part 803 - Medical Device Reporting (MDR). More specifically your firm failed to report within 30 days, whenever you receive or otherwise become aware of information from any source that reasonably suggests that a device may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1). Your firm received 29 reports of burns to users of the Anodyne Therapy device from August 2003 to April 2005. At a minimum your firm failed to submit nine (9) of the reports referencing burns to users to FDA as serious injuries, e.g., Complaints #144 dated 1/2/2004, #858 dated 8/19/2004, #1014 dated 9/13/2004, #1452 dated 1/14/2005, #1457 dated 10/29/2004 concerning two patients, #1625 dated 1/14/2005, #1883 dated 3/8/2005, and #2175 4/26/2005 (FDA 483, Item #5).

#### *Establishment Registration and Device Listing*

We have reviewed your firm's Establishment Registration and Device Listing records. Although you have an active Establishment Registration under Registration Number 1055581, you previously had a duplicate Establishment Registration under Registration Number 30044562499. When this duplicate Establishment Registration was purged from our database, the associated Device Listing for an Infrared Lamp (21 CFR 890.5500) was also purged. Please submit a new FDA Form 2892, Device Listing, to include an Infrared Lamp among your Device Listings.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no applications for premarket approval to which QS regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates for Products for Export will be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure the similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

/S/

Emma Singleton  
Director, Florida District

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Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

MAY 4 2004

WARNING LETTER

VIA FEDERAL EXPRESS

Ms. Kimberly Peterson  
President  
Light Force Therapy, Inc.  
650 East Walnut Street  
P.O. Box 306  
Elizabeth, Colorado 80107

Dear Ms. Peterson:

We are writing to you because your firm is marketing infrared lamp devices known as the "LFT 9000," "Dio LFT 3000," and "Super Nova" for new intended uses that were not cleared or approved by the Food and Drug Administration (FDA). In addition, we believe that certain of your current labeling materials contain false or misleading statements or information.

Under section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act), these products are medical devices because they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. The law requires that manufacturers of medical devices obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly-introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

A review of FDA databases disclosed that your firm obtained premarket notification (510 (k)) clearances for the "Super Nova," "Acubeam," "Acubeam LFT 5000," and "Dio LFT 3000" devices (K001179 and K022888). It is our understanding that your firm no longer sells the Acubeam or Acubeam LFT 5000. The LFT 9000 appears to be an updated model of the Acubeam LFT 5000 that does not require a separate premarket submission prior to commercial distribution for the same indications for which FDA cleared the Acubeam LFT 5000.

FDA cleared the Super Nova and Acubeam (K001179) for the following intended uses:

"The Super Nova and Acubeam are indicated for use to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness and promoting relaxation of

muscle tissue.”

FDA cleared the Acubeam LFT 5000, Dio LFT 3000, and Super Nova (for one additional indication) (K022888) for the following intended uses:

“The Light-Force Therapy line of infrared lamps are indicated for use to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.”

All claims in your labeling and promotional materials must be limited to the cleared indications listed above. However, our review of the following materials revealed that your labeling and promotional materials go beyond these cleared indications:

1. Your firm’s Internet website, <http://www.lightforcetherapy.com>, from which your products are sold.
2. An informational video entitled “LFT 9000 Show #4,” which your firm sends to prospective customers, and which appears as (or is very similar to) a television infomercial through which your firm sells the LFT 9000. The informational video references your website, which offers all the devices for sale.
3. An instructional video entitled “Instructional Video” (Version A) which accompanies the LFT 9000 device sold to customers.
4. An information packet regarding your devices in a folder entitled “LIGHT FORCE THERAPY,” which your firm sends to prospective customers. The information packet contains pricing and other information about how to purchase your devices.
5. A newsletter called “LFT Spring Newsletter -- Spring 2004,” which current or prospective customers can sign up to receive through your website.

These items make statements about intended uses for the LFT 9000, Dio LFT 3000, and/or the Super Nova for which you do not have FDA clearance or approval. Examples of such statements include, but are not limited to, the following:

- “[I]t can be used on about any type of pain.”
- “[I]t even helps relieve stubborn chronic pain.”
- “[W]onderful for conditions like . . . tennis elbow, nerve pain, [and] tension headaches. . .”
- “[H]elps relieve pain from . . . tendonitis [and] bursitis. . .”
- “Light Force Therapy a remarkable therapeutic light”
- “Light therapy.”
- “[I]t is cleared by the FDA to relieve general pain.”
- “Light Force Therapy’s products were cleared by the FDA to relieve pain: safely and effectively.”
- “Light Force Therapy utilizes the technology of light emitting diodes (LEDs) to produce photons of different wavelengths.”

- “Light Force Therapy devices emit energy in the near-infrared spectrum to provide relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness and promoting relaxation of muscle tissue.”
- “[F]or pain sufferers to find fast, effective and safe pain relief for a variety of ailments.”

These indications constitute major changes or modifications in the cleared intended uses of your products, and therefore require a new premarket submission prior to marketing your devices for these new indications. 21 CFR 807.81(a)(3)(ii). Guidance regarding the kind of information you need to submit to FDA in order to obtain clearance or approval for the additional indications is available through the Internet at <http://www.fda.gov/cdrh/devadvice/3122.html>.

Your promotion and introduction into interstate commerce of the LFT 9000, Dio LFT 3000, and Super Nova for uncleared indications violates the law. Specifically, these products are adulterated under section 501 (f)(1)(B) of the Act because you do not have an approved Premarket Approval Application (PMA) to demonstrate that these products are safe and effective for the new uses for which you are marketing them. In addition, the devices are misbranded under section 502(o) of the Act because you have not submitted a section 510(k) premarket notification to the agency of your intent to introduce the devices into commercial distribution for these new uses. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the Act is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81 (b).

During several previous communications with your firm and its representatives, FDA advised you that certain intended uses for which you are now promoting your devices could not be included under your 510(k) clearances. For instance, prior to clearance of 510(k) number K001179, FDA required you to modify indications for “pain” to “minor muscle and joint” pain. With regard to 510(k) number K022888, your firm’s representative (Mr. Lewis Ward of L.W. Ward and Associates) agreed in a November 14, 2002 facsimile to several changes urged by FDA, including the addition of the word “minor” to the indication for joint and muscle pain, and to the removal of your proposed “chronic pain” indication.

Furthermore, the labeling materials listed above as items 1-4 appear to contain false or misleading statements or information, which include but are not limited to the following examples:

- False statements on your Internet website and in your information packet that the devices are cleared by the FDA to relieve “general pain,” that the devices do so “safely and effectively,” and that you “design and manufacture products that meet the Food and Drug Administration requirements for pain relief.”
- False statement in your informational video that the FDA has “reviewed all of our materials and . . . determined that the claims that we make are in fact accurate.” FDA did not review your current materials during the 510(k) process, nor has FDA determined that the claims you make in these materials are accurate.
- Misleading representation of a document on FDA letterhead as being a letter issued to your company granting clearance to your devices and confirming the accuracy of your claims. A review of our records revealed that the letter shown in the informational and instructional videos does not describe any approval or clearance of your products. Moreover, as stated above, FDA did not review your current

materials during the 510(k) process, nor has FDA made any statement as to their accuracy. The letter in your videos is actually the text from a 510(k) summary for the "MedX1000" device from a different company, which lists the LFT 9000 as a predicate device.

Your website, the information packet (e.g., a four-page brochure), the informational video, and the instructional video constitute labeling as defined under section 201 (m) of the Act, and the false and misleading statements therein render your devices misbranded under section 502(a) of the Act. The false and misleading statements specified above, and any similar statements, as well as the letter incorrectly identified as an FDA endorsement of your products, must be removed from the website, the four-page brochure, the videos, your infomercial, and any similar materials you provide to customers or prospective customers.

You should know that these are serious violations of the law that may result in FDA taking regulatory action against you or your product without further notice if you do not act promptly. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your products, or assessing civil money penalties. Also, federal agencies are informed about Warning Letters such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on these matters now. Please let this office know what steps you have taken to correct these problems within fifteen (15) working days from the date you receive this letter. We also ask that you explain how you plan to prevent these problems from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to:

Christy Foreman, Acting Chief  
Orthopedic, Physical Medicine and Anesthesiology Devices  
Division of Enforcement B, Office of Compliance  
Center for Devices and Radiological Health  
Food and Drug Administration  
2098 Gaither Road, HFZ-343  
Rockville, MD 20850

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance or approval and subsequent promotion of your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing and other requirements affect your particular devices, or about the content of this letter, please feel free to contact William Defibaugh at (301) 594-4660, extension 121.

Sincerely yours,

/s/

Timothy A. Ulatowski



Director  
Office of Compliance  
Center for Devices and  
Radiological Health

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Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

CERTIFIED MAIL  
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## WARNING LETTER

FLA-04-25

March 29, 2004

Randall L. Everett, President  
Diomedics, Inc.  
755 State Road 21  
North Melrose, Florida 32666

Dear Mr. Everett:

During inspections of your establishment located in North Melrose, Florida on June 25 and October 27-28, 2003 FDA Investigator R. Kevin Vogel determined that your establishment is a manufacturer and distributor of infrared therapy device(s) (Class II). These products emit energy in the infrared spectrum to provide topical heating for the purpose of elevating and/or maintaining tissue temperature and are devices, as defined by Section 201(h) [21 U.S.C. 5321 (h)] of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator documented violations of the Act causing the device to be adulterated within the meaning of sections 501 (f)(1)(B) [21 U.S.C. 351 (f)(1)(B)] and 501 (h) [21 U.S.C. 351 (h)] and misbranded within the meaning of sections 502(a) and 502(o) [21 U.S.C. 352(a) and (o)] of the Act.

You do not have marketing clearance from FDA to promote and distribute the Pain-X-2000 as being effective for wound management, skin conditions, soft tissue injuries, joint conditions, fracture, chronic pain, head aches, and activation of acupuncture points, as listed in your internet promotions. The promotion of these device(s) for these claims contained in the Pain-X-2000 promotional material represent major modifications in the intended use requiring a new premarket notification submission. 21 CFR 807.81(a)(3)(ii). Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may market your device for these intended uses, your product is also adulterated under 501(f)(1)(B) of the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective.

Your Pain-X-2000 and other new infrared therapy models including Models 500, 1900, 3800, 5700, and Ultimate Portable; Boot System; Clinical A, B and C; the Infra-Red Bed; Model 3800 Headphones, Pads and Probe; Model 1900 Pads; Model 185 Pads, Probe; Model 19 LED Probe and LED Pad; and Model 38 LED Pad are also adulterated under section 501 (f)(1)(B) [21 U.S.C. 351 (f)(1)(B)] of the Act because you did not obtain premarket approval based on information developed by you that shows that the devices

are safe and effective for the claimed intended uses.

Your devices are misbranded under section 502(o) [21 U.S.C. 352(o)] of the Act because a notice or other information respecting your devices were not provided as required by section 510(k), i.e., you did not submit information respecting the intended uses for claims made in your promotions and other new infrared therapy devices to the Food and Drug Administration.

The Pain-X-2000 is misbranded under 502(a) [21 U.S.C. 352(a)] because your website states that the device is "FDA Approved." The Pain-X-2000 was not reviewed under the pre-market approval process, therefore describing your device as "FDA approved" is false and misleading.

The investigator also documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting regulations, Title 21, CFR, Part 803. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501 (h) [21 U.S.C. 351 (h)] of the Act.

Specifically, the investigator noted the following violations:

1. Your firm failed to document that the design of your device(s) followed the approved plan and that the design control requirements are maintained in the design history file as required by 21 CFR 820.30 (b) & (j) (FDA 483, Item #1 dated October 27-28, 2003 and FDA 483, Item #1 dated June 25, 2003).
2. Your firm failed to establish and maintain complete procedures to control the design process of device(s) to ensure that specified design requirements are met as required by 21 CFR 820.30 (a) and (g). Requirements to complete risk analysis were not included in the design control section of the Design Control Procedure, although it now includes descriptions of the design input, verification and validation for each device, it does not require that risk analysis be conducted for each design project (FDA 483, Item #4 dated October 27-28, 2003 and FDA 483, Item #4 dated June 25, 2003).
3. Your firm failed to establish and maintain procedures to assure that all purchased product and services conform to specified requirements as required by 21 CFR 820.50. Critical components such as LEDs and p.c. boards are not tested or inspected to assure that they meet specified requirements prior to processing (FDA 483, Item #2 dated October 27-28, 2003 and FDA 483, Item #2 dated June 25, 2003).
4. Your firm lacks complete training records for all employees as required by 21 CFR 820.25 (b). Documentation for the training of personnel who perform soldering operations was not complete (FDA 483, Item #3 dated October 27-28, 2003 and FDA 483, Item #3 dated June 25, 2003).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to,

seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

/s/

Emma Singleton  
Director, Florida District

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## Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

Via Federal Express  
WARNING LETTER

Neil Camera, President  
Laser Therapeutics, Inc.  
101 Waterside Drive  
Centerville, MA 02632

Dear Mr. Camera:

This Warning Letter informs you of the objectionable conditions found during the Food and Drug Administration (FDA) inspection conducted at your sponsor site. This letter also discusses your verbal and your written reply dated June 20, 2004, to the Form FDA 483 noted violations and requests that you provide a written reply to this letter as well as implement prompt corrective actions. Ms. Sandra P. White, an investigator from the FDA's New England District Office conducted the inspection from April 5 through April 15, 2004. The purpose of the inspection was to determine whether your activities and procedures as a sponsor and monitor for clinical studies of the MediCom a.s. Low Level Laser complied with applicable FDA regulations. The MediCom a.s. Low Level Laser is a device as that term is defined under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

This inspection was conducted under a program designed to ensure that data and information contained in Investigational Device Exemption (IDE) applications, Premarket Approval (PMA) applications, and Premarket Notification [510(k)] submissions are scientifically valid and accurate. The program is also designed to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report prepared by the New England District Office revealed serious violations of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions. At the conclusion of the inspection, Ms. White presented and discussed with you the observations listed on the Form FDA 483 "Inspectional Observations." In your written response, you appear to have adequately addressed several of the observations identified. However, the following violations require further explanation.

**Failure to establish written procedures for monitoring the investigation (21 CFR 812.25);  
Failure to ensure proper monitoring of the investigational study (21 CFR 812.40)**

Pursuant to 21 CFR 812.25, a sponsor is responsible for providing within the investigational plan written procedures for monitoring the investigation. Pursuant to 21 CFR 812.40, a sponsor must ensure proper monitoring of the investigation. You failed to adhere to these requirements, as explained below.

You have no established procedures or guidelines for monitoring any of your ongoing protocols. In your written response you acknowledge that you do not have established monitoring procedures and that you are in the process of formalizing such procedures. Having not seen or reviewed the procedures, FDA cannot determine their adequacy. However, establishing and following complete monitoring procedures should assist you in avoiding recurrence of the problems noted during the inspection.

There is no evidence of having ensured proper monitoring of any of the study sites. You have no documentation of monitoring site visits. When asked about monitoring during the inspection, you stated that on-site visits were not always documented.

**Failure to maintain accurate, complete, and current records relating to an investigation. 21 CFR 812.140(b).**

A sponsor must maintain accurate, complete, and current records of all correspondence with another sponsor, a monitor, an investigator, or an IRB, including required reports. (21 CFR 812.140(b)(1)). A sponsor must also maintain accurate, complete and current records for any nonsignificant risk study that include the name and intended use of the device and the objectives of the investigation, the name and address of each investigator, and the name and address of each IRB that has reviewed the investigation. (21 CFR 812.140(b)(4)). These records must be maintained for at least two years after the date on which the investigation is terminated or completed. (21 CFR 812.140(d)).

You violated these requirements. For example:

With respect to protocol [redacted] submitted to the [redacted] under study number [redacted] and protocol [redacted] submitted twice to the [redacted] under numbers [redacted] and [redacted] some of your electronic records were lost due to destruction by a computer virus and there is no documentation of any hard copy records maintained. Consequently, documentation of these studies is incomplete.

With regard to protocol [redacted] ([redacted]) [redacted] study #[redacted], you were unable to provide the original study protocol as submitted to the reviewing IRB, a copy of your submission request to that IRB's approval letter. You claim to have formally terminated protocol [redacted] with the [redacted] on June 28, 2003, and have no record of any communication between the [redacted] and you following that date. Although you indicated to the investigator that you had not received any contact or correspondence from the [redacted] after that date numerous letters from [redacted] had been sent to you regarding studies over which the [redacted] was of August 4, 2003, informing you of the termination of study [redacted] (enclosed); and a certified letter from Covington & Burling (representing [redacted] dated February 11, 2004, (enclosed) requesting that you cease distribution of [redacted] informed consent forms and referencing the termination of study [redacted].

You also have no documentation that after the termination of your relationship with [redacted] as the reviewing IRB for protocol [redacted] that you informed the clinical investigator(s) involved of this change or instructed them how to proceed given the absence of IRB approval.

Furthermore, in a letter dated February 5, 2005 (sic), you responded to an FDA Warning Letter dated January 12, 2004 to Medicom a.s., identifying Laser Therapeutics as the registered agent of that laser manufacturer. In that letter, you state that you at that time had three ongoing "IRB sponsored clinical trials," identified, and indicate that one of these trials was being overseen by the [redacted]. Yet you have no records of correspondence with the [redacted] with respect to any study after June 28, 2003.

In addition, for any study of a nonsignificant risk device, pursuant to 21 CFR 812.140(b)(4), you should have records clearly identifying for each study the intended use of the device and study objectives, and the name and address of all IREs that have reviewed the study. You do not appear to have such clear records, and have no record indicating the [redacted] as the current IRB for any ongoing study, despite your representations to FDA in the February 5, "2005", letter.

With respect to protocol [redacted] your records are incomplete in many respects. You have claimed that Dr. [redacted] principal investigator of the study, was also the study sponsor. However, the limited records you maintain include the IRB Study Submission Form for study [redacted] dated 6/26/2002, which is more recent than any other record of IRB submission in your files for this study, and which identifies Laser Therapeutics as the sponsor of the study. There is no record of transfer, discontinuation, or final report of the study at this site by Laser Therapeutics and likewise there is no record of disposition of the devices under investigation following dissolution of the business relationship at this site. Lack of any documentation of termination of the study at this site suggests that the study remains your responsibility as the sponsor. Your records regarding all aspects of this study are extremely limited, although you indicated to the FDA investigator that it is particularly troubling as this protocol was originally approved by the [redacted] and as indicated above, the [redacted] maintains that it no longer oversees any ongoing studies of Laser Therapeutics' devices.

Please explain the foregoing record keeping deficiencies and in particular, why you have no documentation of correspondence with the [redacted] subsequent to June 2003. Explain procedures and activities you will undertake to assure in the future that all records are maintained.

Within 15 working days after receiving this letter please provide written documentation of the specific steps you have taken or will take to correct these violations and prevent the recurrence of similar violations in current and future studies. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you.

Send your response to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Compliance  
Division of Bioresearch Monitoring  
Program Enforcement Branch II (HFZ-312)  
2094 Gaither Road  
Rockville, Maryland 20850  
Attention: Mr. G. Levering Keely, BSN, MPA,  
Consumer Safety Officer.

We are also sending a copy of this letter to FDA's New England District Office, One Montvale Ave., 4th Floor, Stoneham, MA 02180. We request that you also send a copy of your response to that office.

The above listed violations are not intended to be an all-inclusive list of violations that may exist in your clinical studies. It is your responsibility as the sponsor to ensure adherence to each applicable requirement of the Act and FDA regulations. In addition to responding to this Warning Letter, we request that you meet with FDA to clarify the conflicting information about several of your studies that results from statements in your February 5, "2005", letter to FDA, the information collected during the April 2004 FDA inspection, and from the correspondence from the [redacted] to your company. You may schedule this meeting by calling Mr. Levering G. Keely at (240) 236-0125.

Sincerely yours,

/s/

Timothy A. Ulatowski

Director

Office of Compliance  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAR 14 2000

WARNING LETTER

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

VIA FACSIMILE AND  
FEDERAL EXPRESS

Mr. Maurice J. Bales  
President  
Bales Scientific, Inc.  
1620 Tice Valley Boulevard  
Walnut Creek, CA 94595

Dear Mr. Bales:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed some promotional material for the Bales Scientific Thermal Image Processor (TIP) and your Photonic Stimulator found on your Internet site at [www.balesscientific.com](http://www.balesscientific.com). Both the TIP and the Photonic Stimulator are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The TIP is classified as a telethermographic system. FDA's regulation at 21 CFR §884.2980(a) classifies telethermographic systems as follows. "[The] [t]elethermograph system [is] intended for adjunctive diagnostic screening for detection of breast cancer or other uses. A telethermographic system for adjunctive diagnostic screening for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories."

Bales' 510(k) premarket notification submission designated 897191 was cleared as a "telethermographic system intended for medical imaging. The TIP uses a HgCaTe type detector element. BSI states that the TIP is for multiple clinical applications, but that product claims will contain all the elements of the 1985 ODE labeling policy on medical thermography, i.e., adjunctive/non-diagnostic."

Although your device is cleared as an adjunctive device, the Agency has reviewed several web pages on your Internet site that imply that the TIP can be used as a stand alone diagnostic device for the detection of breast cancer.

Your web page titled "Breast Health Analysis," found at [www.balesscientific.com/ie/breasthealth/breasthealth.html](http://www.balesscientific.com/ie/breasthealth/breasthealth.html) states the following, "The Bales Algorithms are applied and used to determine Breast Health and subsequent risk factor." Both the title and the text on this page imply that the TIP alone can be utilized to determine the health status of the breast.



On [www.balesscientific.com/ie/breasthealth/vascular/vascular.html](http://www.balesscientific.com/ie/breasthealth/vascular/vascular.html) the web page is titled "Vascular Tree." There are pictorial representations of various views of a woman's breast. Beneath the first picture there is a caption that reads, "Vascular Tree shows cancer (patient1). The third and fourth pictures show side and frontal views of a woman's breast with captions that read, "(left) Image processed to show benign growth (Patient 3). (right) Image processed, shows healthy breast."

At [www.balesscientific.com/ie/breasthealth/localanom/localanom.html](http://www.balesscientific.com/ie/breasthealth/localanom/localanom.html) there is a frontal view of a woman's breast. The web page is titled "Localization of Anomaly and the caption reads, "Suspect Area Map [Step 3]. These images show a cancerous growth in the upper part of the left breast."

Finally, at [www.balesscientific.com/ie/breasthealth/postsurgery/postsurgery.html](http://www.balesscientific.com/ie/breasthealth/postsurgery/postsurgery.html) there are frontal pictures that are said to represent the breast after surgical procedures. The captions are as follows. "(left) The image shows abnormal sympathetic function in the left breast (elevated temperature, five days post surgery). (right) The image shows the sympathetic system's correct response to stress (temperatures are normalized, ninety days post surgery)." The pictures, as well as the captions, imply that the TIP can detect the presence or the absence of breast cancer.

All of the aforementioned web pages promote the TIP device as a stand alone diagnostic tool and not as an adjunctive device. There is no mention of other diagnostic devices such as mammography on any of the above web pages. "Breast Health Analysis" is the title carried on your web page that introduces the other portions of your web site discussion regarding the health of the breast. This title clearly implies that the TIP can be used to determine the presence or absence of breast cancer. The pictorial representations of the breast on the web pages that follow are described as depicting either healthy or cancerous breasts. On these pages there are also no references to the use of other diagnostic tools in determining the presence of breast cancer. This is inappropriate as your device is cleared as an adjunct and not as a stand alone device for the detection of breast cancer.

The Agency also has concerns about the promotion of your Photonic Stimulator. The Bales Photonic Stimulator 510(k) premarket notification submission designated 974468 was cleared to "emit infrared light that penetrates the skin to promote increased blood flow and circulation, thereby providing safe, temporary relief of minor aches and pains where heat is indicated."

Although your clearance does not include the treatment of specific medical conditions, your internet site contains several references to the treatment of specific conditions such as diabetic neuropathy, reflex sympathetic dystrophy (CRPS), headaches, and myofascial pain/thoracic outlet syndrome.

Your web page titled "Photonic Stimulator™ = Chronic Pain Treatment" found at [www.easepain.com/ie/index.html](http://www.easepain.com/ie/index.html) (the easepain site can be reached by the "photonic stimulator" link found on the [www.balesscientific.com/ie/breasthealth](http://www.balesscientific.com/ie/breasthealth) site), contains a picture of the Photonic Stimulator. Below the picture is the following list of medical conditions, "Diabetic Neuropathy, Radiculopathy, Reflex Sympathetic Dystrophy (CRPS), Headache, Myofascial Pain/ Thoracic Outlet Syndrome" and brief descriptions of each condition. In each description, there is reference to how each illness manifests itself in the body by reducing blood flow. The reduction of blood flow is then described as causing pain. On this web page you also describe the Photonic Stimulator as a device that "emits infrared photons that penetrate the skin and soft tissue to stimulate the nerves. This stimulation helps the nerve return to its normal function of blood flow control..." This description of the device along with your descriptions of the medical conditions imply that the Photonic Stimulator can treat each of these conditions.

The next pages on your web site then discuss each medical condition individually and suggest through the use of before and after pictures that the Photonic Stimulator is indicated to treat each condition. On your web page titled, "Diabetic Neuropathy" found at [www.easepain.com/ie/diabetic/diabetic.html](http://www.easepain.com/ie/diabetic/diabetic.html) there is a caption that reads, "the following patients had chronic burning pain in their feet. After Photonic Treatment, the pain disappeared. Please select one of the case studies to follow:" Listed below this caption are three case study selections. Choosing any one of the case study links takes the reader to what the company claims are pictorial representations of before and after treatment of diabetic patients with the Photonic Stimulator.

On [www.easepain.com/ie/radicul/radicul.html](http://www.easepain.com/ie/radicul/radicul.html) the web page is titled, "Radiculopathy." The caption on that page reads, "The following images are examples of Lower Back Pain. Please select one of the case studies to follow:" One of the representative links on this page leads the reader to a graphic representation of a patient's before and after treatment with the Photonic Stimulator.

On [www.easepain.com/ie/reflex/reflex.html](http://www.easepain.com/ie/reflex/reflex.html), the caption reads, "The following patients had Reflex Sympathetic Dystrophy. Please select one of the case studies to follow:" Again there are links to pages which show before and after pictures of patients with Reflex Sympathetic Dystrophy (CRPS) who have been treated with the Photonic Stimulator.

Claims that imply that the TIP can be used as a diagnostic and not as an adjunctive device and claims that the Photonic Stimulator can be used to treat specific medical conditions have misbranded and adulterated the devices within the meaning of sections 502(o) and 501(f)(1)(B) of the Act. Both the TIP and the Photonic Stimulator are misbranded because a notice or other information respecting the devices was not provided to the FDA

as required by section 510(k) and they have not been found to be substantially equivalent to predicate devices for the uses claimed. The devices are adulterated because they are class III devices under section 513(f) of the Act and do not have approved applications for premarket approval in effect pursuant to section 515(a) or approved applications for investigational device exemptions under section 520(g).

FDA's regulations at 21 CFR 801.4 provide that the term "intended uses" of a device refers to the objective intent of the persons legally responsible for the labeling of a device. That intent may be shown by labeling claims or advertising matter or oral or written statements by such persons or their representatives. Making claims that your TIP device can be used as a diagnostic device and claims that your Photonic Stimulator can be used to treat specific medical condition changes the intended use for which the TIP and the Photonic Stimulator were cleared. Pursuant to section 510(k) of the Act and as provided in 21 CFR 807.81(a)(3)(ii), claims that constitute a major change in the cleared intended use of a device require the submission of premarket notification to FDA.

The specific violations in this letter may represent practices used in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to ensure compliance with applicable regulations.

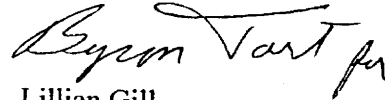
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunctions and/or civil penalties. This letter is not intended to be an all-inclusive list of deficiencies associated with the TIP device or the Photonic Stimulator.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should include steps being taken to address misleading information currently in the marketplace and actions to prevent similar violations in the future. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Send your response to Terri Garvin, Regulatory Counsel, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Los Angeles District Office (HFR-PA-200), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lillian Gill".

Lillian Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health